REMARKS

Claims 20-27 are pending. Claims 20-27 stand rejected.

Rejections under 35 U.S.C. §§ 101 and 112, first paragraph

The Examiner has maintained the rejection of pending claims 20-27 under 35 U.S.C. § 101 as lacking either a specific and substantial asserted utility or a well established utility, and under 35 U.S.C. § 112, first paragraph, for lack of enablement.

As will be discussed in detail below, Applicants respectfully submit that a specific, substantial, and credible utility has been established for the invention defined by the pending claims.

The Manual of Patent Examining Procedure at § 2107 sets forth the Guidelines for Examination of Applications for Compliance with the Utility Requirement. Section 2107 II.(A)(3) states:

> "An invention has a well-established utility if
>
> (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and
>
> (ii) the utility is specific, substantial, and credible."

A rejection for lack of utility and enablement shifts the burden of coming forward with evidence to the applicant to:

> "(i) Explicitly identify a specific and substantial utility for the claimed invention; and
>
> (ii) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established at the time of filing." MPEP § 2107 II.(B)(3).

In the context of such a showing, the Guidelines set forth that unless "countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility" of a statement made by an applicant in relation to an asserted utility, such statements must be accepted as true. MPEP § 2107 II.(D).

As will be illustrated in detail below, Applicants submit they have met the burden imposed by the Utility Guidelines. Applicants believe that a specific and substantial utility for the claimed A07C03 polynucleoties has been identified, and have provided evidence that this utility was well established at the time of filing. Therefore, it is Applicants' belief that the rejection should be withdrawn.

(i) **The claimed A07C03 polynucleotides have a specific and substantial utility as dendritic cell markers.**

Dendritic cells (DC) are specialized antigen-presenting cells that efficiently process and present antigens to, for example, T cells. The study of dendritic cells and their role in the immune response was an emergent field at the time of the invention. At that time, there was a great deal of interest in defining dendritic cells as a cell type. Even more recently, after years of study of dendritic cells and their possible use in clinical settings, much is still published regarding the need for DC markers to aid in their classification and characterization. For example, a 2002 publication on characterization of human blood dendritic cells (submitted herewith as Attachment A) explains:

> "The definition of a DC, to date, has been mainly a functional one. The ability of DCs to take up, process, and present antigens to stimulate T (and B) lymphocytes is accompanied by certain, less consistent, phenotypic and morphological features. DCs lack certain lineage (Lin)-specific markers and express high levels of major histocompatibility complex (MHC) class II molecules; thus the phenotypic definition of DC as $Lin^{-}HLA\text{-}DR^{+}$ has become widespread." MacDonald et. al., Blood 100(13):4512-4520, p. 4512 (2002).

Because there is not a single marker that characterizes dendritic cells, a multitude of markers are needed in order to correctly identify these cells. As for many cells of the immune system, the greater the number of markers used to classify the cells, the better the understanding of the type of cells becomes. In this case, it is clear that the discovery of novel markers is imperative in order to better classify dendritic cells and their precursors.

The polynucleotides defined by the pending claims encode a membrane-bound protein which is stated as belonging to the Ig superfamily of receptors. Page 79, lines 3-7 of the instant specification reads:

> "RT-PCR provides a strong signal only in dendritic cells. Northern blot analysis gives a single band at about 1kb in activated or resting DC and monocytes, but no detectable signal is seen in activated T cells, granulocytes, resting or activated PBL, or B cells."

As such, the claimed polynucleotides have a specific and substantial utility as dendritic cell markers, which are useful in the study and classification of dendritic cells.

Contrary to the Examiner's implication, this utility is no less specific or substantial due to the fact that the A07C03 polynucleotides "cannot even be considered as a marker for any particular type of developmental stage of the various known dendritic cells/monocytes/dendritic cell precursors." (October 28, 2004 Office Action, p. 3). There is not, even at this time, a single marker that specifically characterizes dendritic cells. The identification of the A07C03 receptor and its selective expression on dendritic cells and dendritic cell precursors provides information about two dendritic cell subsets that can be used in conjunction with other phenotypic and functional information to further define, classify and study these subsets of dendritic cells.

(ii) One of ordinary skill in the art would have recognized that the utility of novel dendritic cell markers was well established at the time of filing.

The utility of the present invention as a novel dendritic cell marker would have been readily recognized by one skilled in the art when the present invention was filed. Publications dating from before the priority date of the application up to now, speak of a well-established need to further classify DC and to find a good marker. In the context of definition and classification of dendritic cells, as well as in the study of dendritic cells for various therapies, publication authors take note of the necessity to find markers that are able to select for dendritic cells. Some examples of these publications are attached to this Response as Attachments B, C, and D, for the Examiner's convenience:

Attachment B: Rosenzwajg et al., Blood 15;87(2):535-44 (1996):

> "Characterization of DCs in humans has been confounded both by the lack of exclusive lineage-specific markers and by their low numbers and consequent difficult isolation as pure populations." (p. 535)

Attachment C: Fearnley et al., Blood 89(10):3708-3716 (1997):

> "The isolation of DC or their precursors from blood has been difficult in view of their scarcity and the absence of well-established DC lineage markers." (p. 3708)

Attachment D: Olweus et al., PNAS 94(23):12551-12556 (1997):

> "[C]haracterization of DC progenitors has been difficult due to the lack of selective markers that identify the cells at an early stage of differentiation." p. 12551.

In short, review of Attachments A-D can leave no doubt that one of ordinary skill in the art would have recognized that the utility of novel dendritic cell markers was well established at the time of filing.

CONCLUSION

Applicants submit that claims 20-27 satisfy the requirements of 35 U.S.C. § 101. For the reasons stated above, applicants also submit that claims 20-27 satisfy the requirements of 35 U.S.C. § 112, first paragraph. Accordingly, reconsideration of the rejections and allowance of the claims at an early date are earnestly solicited.

If the undersigned can be of assistance to the Examiner in addressing issues to advance the application to allowance, please contact the undersigned at the number set forth below.

Respectfully submitted,

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